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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,570	DRAKE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/16/07 and the supplemental reply received 8/21/07 have both been entered.

Response to Amendments

Applicant's amendments filed 7/16/07 to claim 1 have been entered. No claims have been cancelled or added in this reply. Claims 1, 2, 5, 7, and 8 remain pending in the current application, of which claims 1, 2, 5, and 7 are being considered on their merits. Claim 8 remains withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, and 7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires that the bacteria and nutrient within the composition be "mixed prior to administration to the subject," which is confusing. It is not clear whether the

claims are drawn to a kit in which components (i)-(iv) are mixed together or whether the components are provided separately. The claim should be amended such that the physical characteristics of the kit, NOT any intended use or manner of using, are particularly claimed. Clarification is required.

Applicant alleges that the amendments to the claims "more clearly identify characteristics of the kit" (Reply, page 4, last paragraph). These arguments have been fully considered, but they are not persuasive. As discussed above, the physical configuration of the kit is simply not clear.

Claim 1 is further indefinite for the following reasons, which have been raised by the amendments to the claims.

Claim 1 is drawn to a kit "adapted for oral administration ... wherein said kit is formulated for oral administration," which is confusing because the nature of the adaptation is not particularly pointed out. Clarification is required. In the interest of compact prosecution, any composition that can be safely administered orally is considered "adapted" or "formulated" for oral administration.

Claim 1 requires that the composition be formulated "to stimulate internal growth of probiotic microorganisms in a subject," but it is not clear what physical attributes are necessarily conferred onto the composition by this limitation. Clarification is required.

Because claims 2, 5, and 7 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2003, U.S. Patent 6,645,506) taken in view of Jaffe (1974, U.S. Patent 3,852,454).

Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45) and an antioxidant (column 17, lines 33-35). Farmer teaches a formulation comprising *Bacillus coagulans* and fructooligosaccharides (column 25, line 62, through column 26, line 4) and mixing said formulation into water (column 20, lines 42-53). Farmer teaches that the

formulation may be modified for administration *via* various means, including oral administration (column 19, lines 36-47).

Farmer does not explicitly teach a composition comprising ascorbate or ascorbic acid.

Jaffe teaches that ascorbic acid was a well-known antioxidant at the time of the invention of Farmer.

A person of ordinary skill in the art would have had a reasonable expectation of success in including ascorbic acid in the composition of Farmer because Farmer suggests adding "known antioxidants," and Jaffe teaches that ascorbic acid was a known antioxidant at the time of the invention of Farmer. The skilled artisan would have been motivated to add ascorbic acid to the composition of Farmer because Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition (column 17, lines 21-42).

A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said composition.

The selection of probiotic bacteria to be included in the composition of Farmer clearly would have been a routine matter of optimization on the part of the artisan of

ordinary skill, said artisan recognizing that Farmer teaches that the bacteria may be one or more of any of numerous probiotic bacteria and that the recited bacteria are art-accepted equivalents column 2, lines 21-32). A holding of obviousness over the cited claims is therefore clearly required. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

While Farmer does not explicitly teach a composition comprising a mixture of probiotic bacteria, the inclusion of multiple different strains (as required in instant claim 7) does not render the instant composition patentable. Farmer specifically contemplates compositions comprising multiple strains (column 2, lines 19-22). In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04. Also see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacteria are art-accepted substitutes for each other. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12). It would have been further obvious for the artisan to add ascorbic acid to the composition of Farmer because Farmer teaches that the inclusion of antioxidants in bacterial compositions facilitate the growth and germination of the bacteria therein (column 17, lines 21-42).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that Farmer only teaches including antioxidants as cosmetic agents, not for facilitating the growth and germination of bacteria (Reply, page 6, first paragraph). Applicant alleges that Farmer does not explicitly suggest a composition with all of the instantly claimed components *(ibid.)*. Applicant alleges that Farmer does not teach or suggest a composition adapted for oral administration (Reply, page 6, last paragraph, through page 7, first paragraph). In support of the nonobviousness of the claimed composition, applicant supplies a declaration under 37 C.F.R. 1.132 by inventor Pamela Drake (hereafter "the Drake declaration") and letters from 8 medical professionals (hereafter "the letters") averring that there is a long-felt need for the instant composition (Reply, page 7, second paragraph, through page 9, first paragraph). These arguments have been fully considered, but they are not persuasive.

Applicant's repeated contention that Farmer does not acknowledge the non-cosmetic properties of ascorbic acid in their composition is confusing. As discussed in a previous Office action, Farmer specifically teaches a motivation for including antioxidants in the composition, *i.e.,* facilitating the growth and germination of the bacteria within the composition (column 17, lines 21-42): "The formulation...of this invention may include other probiotic agents or nutrients for promoting spore germination and/or Bacillus growth...the therapeutic compositions may include, but are not limited to the inclusion of: known antioxidants."

Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See M.P.E.P. §2123. Farmer suggests that all of the claimed components may be included in a single composition, as discussed in the above rejection; the fact that compositions comprising only one, two, or three of the recited components are also taught by Farmer does not constitute a teaching away from a composition that includes all four.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitations "adapted [or formulated] for oral administration" and "to stimulate internal growth of probiotic microorganisms in a subject" do not affect the patentability of the claimed

composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application. The instant claims are drawn to a kit with four components that may be mixed together in a single composition (see above rejections under 35 U.S.C. § 112, second paragraph). Farmer explicitly teaches that his composition is suitable for oral administration. As such, the limitations in claim 1 as to intended use do not render the claimed composition nonobvious.

Regarding the Drake declaration and the letters, the scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results. See, for example, *In re Dill*, 202 USPQ 805 (CCPA, 1979), *In re Lindner* 173 USPQ 356 (CCPA 1972), *In re Hyson*, 172 USPQ 399 (CCPA 1972), *In re Boesch*, 205 USPQ 215, (CCPA 1980), *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983), and *In re Clemens*, 206 USPQ 289 (CCPA 1980). In this case, the probative value of the data provided by applicant is not commensurate in scope with the degree of protection sought by the claim. In light of the species election, the instant claim is drawn to a kit that comprises four components: bacteria; fructooligosaccharides; an antimicrobial agent; and ascorbic acid. The Drake declaration and the letters do not address the composition as claimed. The Drake declaration discusses coadministration of probiotic bacteria with and antimicrobial agent, but the instant claims are not limited to a composition comprising probiotic bacteria. Similarly, the letters describe "a patent-pending product that includes both a probiotic and an antifungal in one kit" (see the Ozanne letter, *e.g.*), and a product that "combines probiotics with NYSTATIN" (see the

Sylwester letter, *e.g.*), but they are silent as to a composition that comprises **any** bacteria and an antimicrobial agent as well as ascorbic acid and fructooligosaccharides.

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988). In this case, the evidence provided by applicant addresses compositions that are far broader in scope than the scope of the instant claims.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wynne et al. (2003, WO 03/033681; reference N) taken in view of Muramatsu et al. (1994, U.S. Patent 5,334,516; reference A) and Costanzo et al. (1996, U.S. Patent 5,518,740; reference B).

Wynne teaches a composition comprising the probiotic bacterium *Lactobacillus pentosus* NCIMB 41114 in combination with an antibiotic (*e.g.*, tetracycline) or

antifungal agent (*e.g.*, fluconazole) (page 6, lines 22-29). The composition of Wynne may be a single dosage form comprising all of the active ingredients or may be a kit with separate components (page 6, lines 29-31). The composition of Wynne may take any of numerous forms and is suitable for oral administration (page 6, lines 9-12 and 19-22). Wynne teaches that coadministering *L. pentosus* NCIMB 41114 with an antibiotic mitigates the side effects or the antibiotics (page 6, line 24).

Wynne does not teach a composition comprising a bacterium and an antimicrobial agent as well as fructooligosaccharides and ascorbic acid.

Muramatsu teaches that fructooligosaccharide is a branched sugar that promotes the proliferation of probiotic bacteria, including *Lactobacillus,* in the intestines of a subject when ingested by said subject (column 1, lines 11-20).

Costanzo teaches a yogurt composition for oral ingestion that comprises probiotic bacteria as well as ascorbic acid (Examples 1-5 at column 10, line 15, through column 14, line 48).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the fructooligosaccharide of Muramatsu and the ascorbic acid of Costanzo in the composition of Wynne because Muramatsu and Costanzo teach that fructooligosaccharide and ascorbic acid may be orally administered. The skilled artisan would have been motivated to include fructooligosaccharide and ascorbic acid in the composition of Wynne because Muramatsu and Costanzo teach that they each increase the number of probiotic bacteria in the intestines, and because Wynne teaches that the bacteria/antimicrobial composition is intended to promote intestinal flora.

The probiotic bacteria of Wynne and Costanzo, the fructooligosaccharide of Muramatsu, and the ascorbic acid of Costanzo all improve the state of intestinal flora. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See M.P.E.P. § 2144.06 and *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

The selection of the form of the composition of Wynne taken in view of Muramatsu and Costanzo would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Wynne teaches that the composition may be administered in any of numerous forms through any of numerous avenues. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include fructooligosaccharide and ascorbic acid in the orally ingestible composition of Wynne because Muramatsu and Costanzo teach that oral administration of these components promotes probiotic bacterial growth in the intestines.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments and the evidence in the Drake declaration and the letters have all been considered to the extent they pertain to this new ground of rejection. The

Drake declaration and the letters indicate that coadministering probiotic bacteria and antimicrobial agents is inventive. Furthermore, applicants allege that the prior art does not teach a composition adapted for oral administration that comprises the claimed components (Reply, page 7, paragraph 1). These arguments have been fully considered, but they are not persuasive.

First, as discussed above, the claims are not limited to compositions comprising probiotic bacteria, but rather to compositions comprising any bacteria. In any case, Wynne explicitly teaches a composition that comprises both probiotic bacteria and an antibiotic or antifungal. Wynne also explicitly teaches an orally ingestible composition. The reply set forth above to the rejection of record also applies to this rejection.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart